CLINICAL LABORATORY BULLETIN November 2004

Web page: http://health.utah.gov/els/labimp

❖ INTRODUCING:

Kathy Anderson	Sample Receiving
Don Berrett	Sample Receiving
Annie McCoy	Toxicology
Paul Pedersen	Sample Receiving
Carol Warenski	Sample Receiving

NOTEWORTHY

✓ **Quality Assessment in Histopathology:** The College of American Pathologists (CAP) offered a new quality assurance program this year for histology slide interpretation. After evaluating performance, the program group concluded good specimens for the survey depends on the ability of the histotechnologist preparing the slide. No other factor such as staining instrument, staining method or the type of stain used consistently resulted in poorer quality slides. Choosing a preparation tech or facility which can routinely provide excellently cut, mounted and stained slides is Priority 1 for the clinician reading and interpreting histology slides. Keep up the good work, histotechs.

✓ **Re-spin Serum Separator Tubes?:** Do you receive specimens collected offsite in serum separator tubes? Are you tempted to re-spin them now they have had more time to completely clot? The National Committee on Clinical Laboratory Standards (NCCLS) says don't be tempted. Research shows the gel may not form a complete barrier if you use a fixed-angle centrifuge. You probably have such a centrifuge as they are much cheaper than the swinging bucket type. Another factor against respinning is most authorities feel a small amount of serum remains on top of the cell layer under the gel. Over time the red blood cells (RBC) leach additional analytes (such as potassium (K) into the serum. Respinning will add extra K to the sample artificially increasing the result. Some studies show as much as 0.6 mmol/L increase in K results after respinning.

✓ **Urine Dipstick Test - Simple:** The urine dipstick test has been CLIA waived from the beginning (1992). It is a simple test to perform. There are automated readers to help testing personnel with timing and color interpretation. What could be easier? Accurate test results rely on more than correct test performance. Read the package insert. This is that thick group of papers stuffed inside the box you throw away when you get out a new bottle. Different manufacturers may have different methods to test the same analyte in urine.

CONTENTS

What interferes with one method may not interfere with another method. The insert I read gave the following examples of interfering substances (this is not the entire list – takes up too much room).

Glucose: ketones, ascorbic acid (AA), specific gravity

Bilirubin: colored compounds, AA, specimen not fresh

Ketone: L-Dopa, colored compounds

Specific Gravity: protein, pH, chlorhexidine

Occult Blood: protein, specific gravity, bleach (some people think you will find out they use drugs so they adulterate the specimen), AA, bacteria

Protein: alkaline urine, chlorhexidine

Urobilinogen: colored compounds, antibiotics, storage temperature, time

Nitrite: pyridium, urine voided before remaining in bladder at least 4 hrs, AA, specific gravity, lack of dietary nitrate

Leukocytes: glucose, specific gravity, antibiotics, boric acid, colored compounds

Before requesting additional, expensive tests, take a good history and check for some of these interfering substances.

✓ **Testing for STD Old & New:** An article in February's MLO by Drs. Hall and Klausner from the University of California, San Francisco discussed available testing for various sexually transmitted diseases (STD).

Syphilis: direct specimen testing =
1. Dark field microscopy (75% sensitive with adequate specimen, excellent microscopist and high treponeme concentration)
2. Direct fluorescent antibody (DFA) stain (99% with adequate specimen, can be used for oral specimens)

Syphilis serology testing =
1. Rapid plasma Reagin (RPR)
2. Venereal disease research laboratory (VDRL) slide test
3. Fluorescent treponemal antibody absorption (FTA-Abs)
4. Microhemagglutination antibody assay (MHA-TP)
5. Particle agglutination (TP-PA)

Serology sensitivity ranges from 75%- 85% in primary syphilis to 99% in secondary syphilis.

Neisseria gonorrhoeae (NG) = 82 to 99% based on specimen source and disease prevalence
1. Gram stain / culture (variable by person, method)
2. Nucleic acid amplification (NAAT) including probe hybridization (similar to culture)

Chlamydia trachomatis (CT) =
1. Cell culture (variable by lab method)
2. NAAT including probe hybridization (better than culture)
3. Rapid point of care tests (lower sensitivity)

Trichomonas vaginalis (TV) =
1. Wet Mount (variable by person <70%)
2. Culture (slightly increased sensitivity)
3. Kit tests (immunoassays, latex agglutination, nucleic acid-based) hard to say as they are compared to culture which is already less than 75%

Herpes simplex virus (HSV) = diagnosis is insensitive and nonspecific
1. Culture (variable)
2. Serology (better in high risk populations)
3. Western blot antibody (80% to 98% but time dependent)
4. DFA (low sensitivity)
5. Tzanck prep (insensitive and non-specific)

For all the STDs other tests are available outside the USA, but not yet cleared by FDA for use here.

✓ **INR Checklist:** Give your patients the most accurate prothrombin time results:
Collect all specimens in 3.2% citrate.
Determine the reference range for your current reagent lot number/instrument on your patients.

Use the geometric mean of your reference range to calculate international normalized ratio (INR).

Check the insert for the current international sensitivity index (ISI) for your instrument (changes with reagent lot changes) and make sure that is the number in your calculations.

Be sure your calculations use ISI as an exponent and not as a multiplication number.

Periodically check the calculation process for accuracy (especially right after a lot change).

✓ **Determining Fetal Hemoglobin Bleed to Administer Appropriate RhoGam Dose:** William G. Finn, MD from the University of Michigan Medical School advises against using blood gas co-oximeter fetal hemoglobin results to determine fetal-maternal hemorrhage. RhoGam package inserts instruct users on how much to give Rh negative mothers delivering Rh positive infants. More RhoGam is given if fetal blood has leaked into the mother's system. Dr. Finn states in the September, 2004 issue of CAP Today the co-oximeter method detects hemoglobin in lysed cells. Adults have some fetal hemoglobin in their blood. To determine if the baby's blood cells actually entered the mother's circulation, the standard fetal red cell quantitation tests (acid elution/Kleihauer-Betke (K/B) or flow cytometry) must be done. Some screening tests exist to rule out a "bleed" such as rosette testing or semi-quantitative gel agglutination assay. Both tests require K/B confirmation and may take the same amount of time to perform.

✓ **FDA letter on automated susceptibilities:**

The Federal Drug Administration (FDA) sent a letter to automated antimicrobial susceptibility test manufacturers following confirmation by CDC of a third USA vancomycin resistant *Staphylococcus aureus* (VRSA) isolate. The letter states in part:
"Until automated and other commercial systems can be evaluated for reliability with relevant organisms, clinical laboratories performing such testing should be aware of this potential shortcoming of these systems and should use methods that have been shown to reliably detect the strains that have been described. At present, non-automated MIC methods (e.g., broth microdilution or agar dilution) with a full 24-hours incubation before reading results are recommended. The CDC previously reported that BHI agar supplemented with 6 ug/mL vancomycin is useful for detecting staphylococci with reduced susceptibilities to vancomycin (JCM 1998; 36:1020-7) and that this method is also reliable with the three recognized VRSA isolates."

You may contact Sally Selepak at 301-594-2096 with technical questions about the letter.

Utah's Laboratory Improvement will offer a susceptibility update workshop in April (see Continuing Education in this bulletin).

✓ **Difficult phlebotomies:** The October issue of Phlebotomy Today states collection tubes for complete blood count (CBC) testing filled to 80% capacity (4/5 full) will give the following inaccurate patient results. A white blood count (WBC) of 3.2 will read 2.4 and a hemoglobin (Hbg) of 10.1 will read 8.6. To view the entire article, see www.phlebotomy.com.

✓ **Lipemic specimens for CBC:** Dr. Robert Novak gave three suggestions in the July, 2004 issue of CAP Today on what to do when you receive a lipemic specimen for CBC testing. Most hematology analyzers state lipemia interferes with accurate hemoglobin determination. With inaccurate Hbg, calculated values such as MCH and MCHC are also inaccurate. Dr. Novak suggests:

1. Report hematocrit, RBC, MCV, WBC and platelet count. Note Hbg cannot be determined due to a lipemic sample. Request another sample after the patient fasts 2 to 3 hours.

2. Determine a whole blood Hbg (Hemocue) and report it with the other reliable parameters (indicating the test methodologies).

3. Do a saline replacement. Centrifuge the specimen, remove the plasma and replace it with an equal amount of saline. Test the sample and report. (This method seems prone to error.)

My suggestion (#4) is to reject the entire specimen, request a new one, and test one that is acceptable for your instrument.

✓ **The trouble with plastic tubes:** As more labs switch from glass to safer plastic phlebotomy tubes, we will see problems listed in the literature. Such cautions were noted in the June 2004 issue of CAP Today.
The shelf life of the vacuum in a plastic tube is shorter than in a glass tube.
Altitude decreases the vacuum in a plastic tube resulting in short draws in smaller tubes (from our own Dr. Sterling Bennett at LDS Hospital).

Plastic additive tubes require twice as much mixing – and don't skimp on the time.
Plastic clot tubes have an added clot activator since the plastic slows clotting.
Validate all your test results (not just one chemistry analyte but the entire test menu) for accuracy – especially coagulation. You would need to collect patient specimens in both tubes to adequately compare. Some one else's published study may not mimic your reagent, instrument, altitude or humidity combination.

Plan ahead before switching. Each of the above problems can be solved and it might be worth the effort to prevent one hepatitis or HIV exposure if the employee is "I".

FROM THE PATIENT'S CHART

"Occasional, constant infrequent headaches."

☆ Feature ☆

I THOUGHT YOU KNEW WHAT I MEANT TO SAY!

Susan Hopkins is an assistant editor for Advance. She wrote an article, "Leadership Outlook – Effective Communication Strategies" in the October, 2004 issue. Her points made a "light" go on in my head.

Most laboratorians came into the field because they are content doing tasks and doing them well. They can be left alone. They don't need constant communication with others to do their tests once they know how. Sound familiar? They let their test reports speak for themselves.

Have you ever had a lab manager content to stay in the office and email you without needing to actually see you until the annual holiday party? Maybe you had a supervisor that seemed to be hovering and had to be 3 inches from your face to make certain you were paying attention to each verbal communication. Hopefully, your experiences have been somewhere in-between these extremes.

Susan Hopkins feels there is no "best" form of communication. All forms have their place in our lives. Susan quotes Nancy Riesz, MBA, MT(ASCP) who is a performance professional for Success Catalyst in North Bend, Ohio.

Face to Face: "All important conversations and bad news are best done in person. Also, when recognizing or rewarding an employee, be sure to do so in person. Following up with a hand

written note reinforces your comments" states Ms. Riesz.

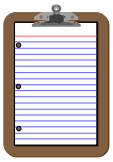
Telephone: Good for long distant communication. Good for group meetings when employees are spread out and can't leave work for meetings. **Not** good to pick up the body language that tells what a person is truly feeling and thinking.

E-mail: Ms. Riesz says, "E-mail is expedient when factual information of moderate to low importance needs to be dispersed to larger numbers of people or to various locations quickly. Written communication in all forms loses both body language and tone of voice, the most important indicators of what the other person(s) is thinking and feeling."

The higher a person is in the management scheme, the more he/she needs to listen rather than talk. Remember the adage "I can't hear what you are saying because what you are doing rings so loudly in my ears"? Riesz explains, "The function of listening is to understand what the other person is saying, not necessarily to agree with it. Pay particular attention to the feelings being expressed. If they are different than the words being spoken, stop and acknowledge the feeling you are sensing. Feelings contain our real messages. If you ignore feelings, true communication will not occur."

- ✓ pay attention
- ✓ tune to body language, feelings and words
- ✓ ask to clarify
- ✓ summarize or paraphrase for understanding

GOOD LUCK



CLIA BITS

ADDITIONAL WAIVED TESTS:

° Polymedco Poly Stat Strep A Liquid Test

° Stanbio Hemoglobin Analyzer

° Trinity Biotech Uni-Gold HIV

° Immunostics Detector Strep A Direct

° Orasure Oraquick Advance Rapid HIV-1/2 Antibody Test (oral fluid, fingerstick whole blood and venipuncture whole blood)

° Hemocue HB 201 DM + System

° Accu-Stat Drugs of abuse Home Test Cup

° Piccolo Point of Care Chemistry Analyzer (lipid panel reagent disc for whole blood)

° Genzyme OSOM Ultra Strep A Test

° Clearview Strep A Exact Dipstick

° Thryo Test Whole Blood TSH Test

° Bristol-Myers Squibb Co. Choice DM (total glycated hemoglobin)

° PEP Performance Enhanced Products Strep A Cassette test and Strep A Dipstick

° Applied Biotech One Step+ Mono Test

° Applied Biotech Truview Mono Test

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The Coalition for Phlebotomy Personnel Standards is seeking to improve education, training and perhaps licensing for phlebotomists in the USA. For additional information check www.phlebotomy.com.

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The final CLIA regulation lessened many microbiology quality control (QC) frequency

requirements. Any specialty or subspecialty rules override general QC requirements. For example, you must still check Gram stain quality each week of testing not just each batch or shipment as with some other stains.

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The most current Circular of Information for Blood and Blood Components is at http://www.fda.gov/cber/gdlns/circbld.pdf Each facility preparing or distributing blood products must have the most current copy available to all employees and product users.

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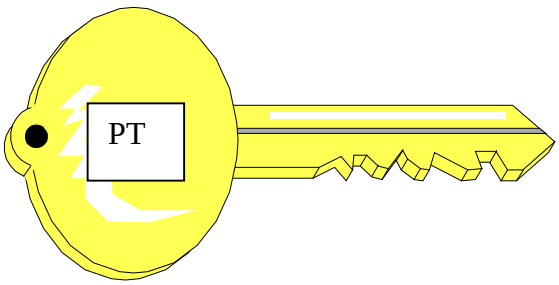
There is an excellent article on reportable range verification in the September/October 2004 issue of COLA Insights. Any new test, change in manufacturer for the same test, test added to an existing instrument's menu, or a new instrument must have the reportable range verified before being used on patients. This requirement is different than "reference" or "normal" ranges for a test. Only waived methods are exempt under CLIA. Information on obtaining a copy of the complete article can be found at www.cola.org.

Equals

"2000 pounds of Chinese soup: Won ton"



With the addition of the MIME to the Maryland State approved cytology pap smear proficiency testing (PT) programs, all CLIA Certificate of Compliance cytology labs will be required to enroll for next year. Remember each cytologist (any one reading pap smears) must enroll – not just each CLIA number. Judy Yost said there will be no sanctions during the first year of the program. Check the CLIA website for latest information (www.cms.hhs.gov/clia).

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CAP and WSLH announced new PT programs and educational materials available next year. Contact them directly for information (CAP = 800-323-4040, WSLH = 800-462-5261).

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Jannette Pappas, PhD, with IHC shared some information with the CLIA surveyors on problem resolution for iSTAT and API PT samples for pH. Because the aqueous, non-buffered samples sent by the PT company were unstable, the testing personnel discovered they must shake samples vigorously and add the sample to the cartridge immediately upon opening. The nature of the sample made this treatment (different than patients) acceptable.

SAFETY

Streptococcus pneumoniae isolates can be typed by CDC only if they represent a vaccine failure. The Utah Public Health Lab has not found a reference lab that offers typing.

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A tragic death occurred in a Michigan Department of Community Health Bureau of

Laboratories worker in 2000. The person acquired a fatal infection working with a *Neisseria meningitidis* isolate. All laboratories performing procedures on specimens or cultures that may contain the organism are encouraged to have a properly working biological safety cabinet.

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Even after the Occupational Safety and Health Administration's (OSHA) update to the bloodborne pathogens regulations in 2001, there are still between 600,000 and 800,000 needlestick injuries reported in health care workers each year. Don't be a statistic. Perform the annual "safer sharps" evaluation carefully. Purchase the best equipment available. Train people adequately. Make certain the procedures are done correctly.

"Reputation is what you are perceived to be. Character is what you are."
John Wooden

CONTINUING EDUCATION

Bureau of Laboratory Improvement (BLI)

U-87 A copy of the CD from this year's grant writing workshop is available from the National Laboratory Training Network (NLTN). The workshop was sponsored by the National Center for Public Health Laboratory Leadership from the Association of Public Health Laboratories. Utah facilities contact Rebecca Christiansen, State Training Coordinator, (801-584-8471) to borrow a copy.

BLI is offering an all day course on the latest packaging and shipping regulations February 14, 2005. Saf T Pak is providing the speaker. There are still 20 available places.
BLI is offering an all day course on antibiotic resistant bacteria susceptibility testing in April.

Contact Rebecca for additional information.

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Applied Phlebotomy Video Series

Contact the Center for Phlebotomy Education, Inc. at www.phlebotomy.com for information.

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NCCLS CONSENSUS DOCUMENTS

In 2005 the National Committee on Clinical Laboratory Standards will become Clinical and Laboratory Standards Institute. You can see their new publications list at www.nccls.org.

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NLTN

CDC created a DPDx program to assist laboratorians identify parasites and maintain expertise in parasitology. There is information on telediagnosis assistance; training CDs; and other topics at www.dpd.cdc.gov/dpdx

The Kentucky Board of Emergency Medical Services offers a free Web-based WMD training, "Terrorism Awareness with Pediatric Emphasis", at www.kiprc.uky.edu/trap

Focus Technologies offers P.A.C.E. credits and approved CE contact hours via their web-conferences. Their focus is infectious disease professionals. http://focusevents.webex.com

P.A.C.E. credits are also available from Abbott Diagnostics in their "Explorations and Innovations" website accessed at www.abbottdiagnostics.com'Ei/default.cfm

NLTN Webspace: www.aphlorc.org Choose "NLTN Webspace". User name is nltn; password is "training".

Fred Miya, MD, PhD, pathologist, laboratory director, CLIA regulation expert, and good friend passed away November 25, 2004 subsequent to a serious illness.

Aloha Oui. We miss you.